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OSOM Influenza A&B Test
510(k)

K051244

510(K) SUMMARY

Pursuant to Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, Genzyme Corporation is providing a summary of the safety and effectiveness information available for the OSOM® Influenza A&B Test.

1. Sponsor/Applicant Name and Address:

   Genzyme Corporation
   One Kendall Square
   Cambridge, MA 02139

2. Sponsor Contact Information:

   Fred D. Lasky, Ph.D.
   Director, Regulatory Affairs
   Phone: 617.591.5512
   FAX: 617.768.9592
   Email: fred.lasky@genzyme.com

3. Date of Preparation of 510(k) Summary:

   May 13, 2005

4. Device Trade or Proprietary Name:

   OSOM Influenza A&B Test

5. Legally Marketed Devices to which Equivalence is Being Claimed:

   Quidel QuickVue® Influenza A+B Test (K 031899)

6. Device Description:

Intended Use

The OSOM Influenza A&B Test is an in vitro diagnostic immunochromatographic assay intended for the qualitative detection of influenza A and influenza B viral nucleoprotein antigens from nasal swab specimens in symptomatic patients. It is intended to aid in the rapid differential diagnosis of influenza A and/or B viral infections. This test is not intended for the detection of influenza C. viruses. A negative test is presumptive and it is recommended these results be confirmed by cell culture.

Cross-reactivity with respiratory viruses other than influenza viruses has not been evaluated. The user is responsible for determining the cross-reactivity of other respiratory viruses with this test.

Principle of the Device

The OSOM Influenza A&B Test consists of a test stick that separately detects influenza A and B. The test procedure requires the solubilization of the nucleoproteins from a swab by mixing the swab in Extraction Buffer. The test stick is then placed in the sample mixture, which then migrates along the membrane surface. If influenza A and/or B viral antigens are present in the sample, it will form a complex with mouse monoclonal IgG antibodies to influenza A and/or B nucleoproteins conjugated to colloidal gold. The complex will then be bound by another mouse anti-influenza A and/or B antibody coated on the nitrocellulose membrane. A pink to purple control line must appear in the control region of the stick for results to be valid. The appearance of a second and possibly a third light pink to purple line will appear in the test line region indicating an A, B or A and B positive result.

8. Comparison of Technological Characteristics of Genzyme OSOM Influenza A&B Test with Legally Marketed Device:

The similarities with, and differences between, the OSOM Influenza A&B Test and the Quidel QuickVue® Influenza A+B Test device are described in Table 1.

Table 1: Summary of Device Similarities and Differences

	OSOM Influenza A&B Test	Quidel QuickVue® Influenza A+B Test
Intended use	Intended for the qualitative detection of influenza A and influenza B viral antigens from nasal swab specimens. It is intended to aid in the rapid differential diagnosis of influenza A and/or B viral infections. The test is for use in clinical laboratories, health clinics, and physician office laboratories.	Intended for the rapid, qualitative detection of influenza type A and influenza type B antigens from nasal swab, nasal wash and/or nasal aspirate specimens. This test is intended for use as an aid in the rapid differential diagnosis of acute influenza type A and type B virus infection.
Assay Format	Lateral flow immunoassay	Lateral flow immunoassay
Specimen	- nasal swabs	- nasal swabs - nasal wash - nasal aspirate
Antibodies (labeled and capture)	Mouse monoclonals	Mouse monoclonals
Conjugate	Colloidal gold	Latex
Objective Test Line	Pink to purple line	Red line
Internal Control	Yes – red line	Yes – blue line
Time To Result	10 minutes	10 minutes

9. Agreement with Viral Culture:

The performance of the OSOM Influenza A&B Test was analyzed compared to viral culture for both influenza A and influenza B. Samples analyzed were from nasal swabs. The results of the comparison of the OSOM Influenza A&B Test are:

	Nasal Swab	
	Influenza A (n = 383)	Influenza B (n = 383)
Sensitivity	73.8%	60.0%
Specificity	96.4%	96.4%
Agreement	90.1%	91.6%

A total of 383 subjects were enrolled in the study. Of the 383 samples, 132 samples were from pediatric subjects (2-19 years) and 251 samples were from adults (> 20 years). The OSOM Influenza A&B Test was compared to cell culture to determine the comparative clinical sensitivity and clinical specificity for detection of influenza A and influenza B in nasal swab specimens.

Comparison of OSOM Influenza A&B Test to Cell culture: Nasal Swab

Flu A

OSOM Influenza A&B	Culture A+	Culture Negative		Total
A+	79	9[1]		88
A+B+	0	1[2]		1
Negative	28[3]	266		294
Total	107	276		383

Clinical sensitivity: 73.8% (79/107)

(95% CI 64.4% - 81.9%)

Clinical specificity: 96.4%. (266/276)

(95% CI 93.4% - 98.2%)

Polymerase Chain Reaction (PCR) was performed on specimens that gave inconsistent results. This assay is not FDA approved or cleared. These results are provided for information only.

PCR Results: [1] 5 Positive, 4 Negative

[2] 1 Negative

[3] 24 Positive, 2 Negative, 1 B Positive, 1 Quantity Not Sufficient (QNS)

Flu B

OSOM Influenza A&B	Culture			
	B+	Negative		Total
B+	30	11[4]		41
A+B+	0	1[5]		1
Negative	20[6]	321		341
Total	50	333		388

Clinical sensitivity: 60.0% (30/50)

(95% CI 45.2-73.6%)

Clinical specificity: 96.4% (321/333)

(95% CI 93.8% - 98.1%)

Polymerase Chain Reaction (PCR) was performed on specimens that gave inconsistent results. This assay is not FDA approved or cleared. These results are provided for information only.

PCR Results: [4] 10 Positive, 1 Negative

[5] 1 Negative

[6] 19 Positive, 1 Negative

Assay Reproducibility

A reproducibility proficiency study was conducted to demonstrate that the OSOM Influenza A&B Test will perform acceptably in the hands of nurses, nurse practitioners and physicians' office personnel. A panel of swabs including negative (no virus), strong negative (below the limit of detection), low (near the limit of detection) and mid viral levels for influenza A and B were coded and masked to the operators. This study was conducted with three operators at three health centers in the eastern United States (2 physician's offices and 1 clinic site) and at Genzyme Diagnostics. The overall accuracy was 97% for flu A and 94% for flu B. Two invalid tests were considered as incorrect results in each analysis. We never saw the education level and experience of the testers, This is a CLIA waver labeling issue.

	Correct Response for Flu A		Lower 95% Confidence Interval	Upper 95% Confidence Interval
A - Strong Neg	12/12	100.0%	73.0%	100.0%
A - Low	23/24*	95.8%	78.9%	99.9%
A - Med	11/12*	91.7%	61.5%	99.8%
B - Strong Neg	12/12	100.0%	73.0%	100.0%
B - Low	23/24	95.8%	78.9%	99.9%
B - Med	11/12	91.7%	61.5%	99.8%
AB - Med	12/12	100.0%	73.0%	100.0%
Negative	48/48	100.0%	92.5%	100.0%
Total	152/156*	97.4%	93.6%	99.3%

	Correct Response for Flu B		Lower 95% Confidence Interval	Upper 95% Confidence Interval
A - Strong Neg	12/12	100.0%	73.0%	100.0%
A - Low	23/24*	95.8%	78.9%	99.9%
A - Med	11/12*	91.7%	61.5%	99.8%
B - Strong Neg	11/12	91.7%	61.5%	99.8%
B - Low	21/24	87.5%	67.6%	97.3%
B - Med	11/12	91.7%	61.5%	99.8%
AB - Med	12/12	100.0%	73.0%	100.0%
Negative	46/48	95.8%	85.7%	99.5%
Total	147/156*	94.2%	89.3%	97.3%

*invalids due to insufficient volume or no control line

Analytical Specificity and Cross-reactivity

The OSOM Influenza A&B Test was evaluated with 25 bacterial isolates. Bacterial isolates were tested at a concentration of approximately ≥108 cfu/mL. Very high levels of Staphylococcus aureus (>9x108 cfu/mL) produced a positive result. All other bacteria listed gave negative responses. Cross-reactivity with other known respiratory viruses was not evaluated. Only influenza isolates were tested.

Bacterial Panel:

Acinetobacter calcoaceticus
Bordetella pertussis
Candida albicans
Corynebacterium diphteriae
Enterococcus faecalis
Enterococcus gallinarum
Escherichia coli
Haemophilus influenza
Klebsiella pneumoniae
Legionella pneumophilia
Moraxella catarrhalis
Mycobacterium avium
Mycobacterium tuberculosis
Neisseria meningitidis
Proteus mirabilis
Proteus vulgaris
Pseudomonas aeruginosa
Serratia marcescens
Staphylococcus aureus
Staphylococcus epidermidis
Streptococcus Group A
Streptococcus Group B
Streptococcus mutans
Streptococcus pneumoniae
Torulopsis glabrata

Influenza A/B Panel testing

A total of 46 human and animal influenza strains were tested with the OSOM Influenza A&B test. Viral titers (TCID50) for A/Kitakyushu/159/93 (H3N2) and B/Lee/40 were determined by inoculating MDCK cells, followed by standard procedures for cell culture viral assays. Aliquots of these controls with known TCID50 were then used to establish a standard curve in an ELISA assay. The concentrations of other influenza viruses were determined indirectly using the ELISA assay after the viruses had been inactivated. Influenza viruses were tested at an ELISA estimated TCID50 as listed in the table below.

All influenza virus isolates gave positive results with the test line at the expected location for the A, B and animal (positive for influenza A) isolates.

Influenza A strains:	Sub-type	Estimated ELISA $TCID_{50}$/mL
Beijing/262/95	H1N1	8.25E+07
Brazil/11/78	H1N1	NA
Chile/1/83	H1N1	NA
New Jersey/8/76	H1N1	2.78E+08
Taiwan/1/86	H1N1	3.47E+07
Guizhou/54/89	H3N2	7.54E+07
OMS/5389/88	H3N2	NA
Beijing/32/92	H3N2	3.97E+06
England/427/88	H3N2	4.73E+07
Johannesburg/33/94	H3N2	1.61E+07
Leningrad/360/86	H3N2	2.50E+06
Mississippi/1/85	H3N2	NA
Philippines/2/82	H3N2	9.75E+07
Shangdong/9/93	H3N2	1.67E+08
Shanghai/16/89	H3N2	3.49E+08
Shanghai/24/90	H3N2	NA
Sichuan/2/87	H3N2	NA
Kitakyushyu/159/93	H3N2	3.19E+08
Akita/1/94	H3N2	2.90E+08
Beijing/262/95	H1N1	1.71E+08
Yamagata/32/89	H1N1	7.28E+07
New Caledonia/20/99	H1N1	6.86E+07
Panama/2007/99	H3N2	1.40E+08
Wyoming/03/03	H3N2	7.40E+06
Fujian/411/02	H3N2	6.12E+07

Influenza B strains:	Sub-type	Estimated ELISA $TCID_{50}$/mL
Ann Arbor/1/86		NA
Beijing1/87		1.04E+07
Guangdong/120/2000		6.44E+07
Hongkong/8/73		1.74E+07
Panama/45/90		3.79E+07
Singapore/222/79		4.84E+07
Yamagata/16/88		1.78E+07
Lee/40		2.13E+08
Mie/1/93		4.84E+07
Guangdong/05/94		1.27E+07
Johannesburg/5/99		5.87E+07
Shandong/7/97		4.41E+07
Shanghai/361/2002		NA

Animal influenza strains:	Sub-type	Estimated ELISA $TCID_{50}$/mL
A/Duck/Singapore-Q/F119-3/97	H5N3	1.65E+08
A/Equine/Prague/56	H7N7	5.37E+06
A/Duck/Wisconsin/1120/82	H5N3	2.30E+08
A/Hong Kong/483/97	H5N1	1.06E+08
A/Hong Kong/213/2003	H5N1	1.84E+08
A/Turkey/Ontario/71	H7N3	8.12E+07
A/Mallard/Wisconsin/479/79	H7N3	2.08E+08
A/Mallard/Saskatchewan/38/81	H7N3	2.46E+08

Although this test has been shown to detect cultured avian influenza viruses, including avian influenza A subtype H5N1 virus, the performance characteristics of this test with specimens from humans infected with H5N1 or other avian influenza viruses are unknown

Interfering Substances

The following potential interferents were tested and were found to have no affect on the performance of the OSOM Influenza A&B Test.

Potential Interferent	**Concentration**
Acetyl salicylic Acid	20 mg/mL
Acetamidophenol	10 mg/mL
Chlorpheniramine maleate	5 mg/mL
Dextromethorphan HBr	20 mg/mL
Diphenhydramine HCl	5 mg/mL
Ephedrine HCl	20 mg/mL
Guiacol Glyceryl Ether	20 mg/mL
Oxymetazoline HCl	10 mg/mL
Phenylephrine HCl	100 mg/mL
Phenylpropanolamine	20 mg/mL
Whole Blood	2%
OTC Throat Drops	
Throat Drop (Halls)	25%
Throat Drop (Zinc)	25%
Throat Drop (Ricola)	25%
OTC Nasal Sprays	
Nasal Spray (Zicam)	10%
Nasal Spray (Afrin)	10%
Nasal Spray (Vicks Sinex)	10%

Note: A very high hemoglobin concentration could interfere with the interpretation of the test result.

Analytical Sensitivity

Dilutions of influenza A Kitakyushyu/159/93 (H3N2) and for influenza B Lee/40 virus were run in triplicate on three lots of the OSOM Influenza A&B Test. The approximate detection limits of the OSOM Influenza A&B Test are 4.4 x 104 TCID50/test for influenza A and 1.44 x 105 TCID50/test for influenza B.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 2 1 2006

Fred D. Lasky, Ph.D
Director of Regulatory Affairs
Genzyme Corporation
500 Kendall Street
Cambridge, MA 02142

Re: k051244
Trade/Device Name: OSOM® Influenza A&B Test
Regulation Number: 21CFR 866.3330
Regulation Name: Influenza Virus Serological Reagents
Regulatory Class: Class I
Product Code: GNX
Dated: February 13, 2006
Received: February 15, 2006

Dear Dr. Lasky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

Indications for Use

510(k) Number (if known): K051244

Device Name: **OSOM® Influenza A&B Test**

Indications For Use: k 051244

The OSOM Influenza A&B Test is an in vitro diagnostic immunochromatographic assay intended for the qualitative detection of influenza A and influenza B viral nucleoprotein antigens from nasal swab specimens in symptomatic patients. It is intended to aid in the rapid differential diagnosis of influenza A and/or B viral infections. This test is not intended for the detection of influenza C viruses. A negative test is presumptive and it is recommended these results be confirmed by cell culture.

Cross-reactivity with respiratory viruses other than influenza viruses has not been evaluated. The user is responsible for determining the cross-reactivity of other respiratory viruses with this test.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K051244